510(k) Number: K093748

FEB 24 2010

Date:

510(k) Summary

Submitter of 510(k)	Dental Direkt of Amerika UG (haftungsbeschraenkt) Pappelweg 6 32139 Spenge Germany
Contact Person	Gerhard de Boer (General Manager) Tel 0049 / 5225-8 6319-0 Fax: 0049 / 5225-8 6319-99
Establishment Registration Number	Pending
Date Prepared	November 23, 2009
Trade Name of Device	DD Bio Z, DD Bio Z-transpa
Common name	Powder, Porcelain
Classification name	Porcelain powder for clinical use (21 CFR 872.6660, Product Code EIH)
Classification	Class II
Predicate Devices	K081263 H.C. Starck Ceramics StarCeram K051462 DENTSPLY International Cercon Base K072569 Metoxit CAM blanks
Device Description and Intended Use	Dental Blanks made of DD Bio Z or DD Bio Z-transpa are dental materials (semifinished products) made of yttrium stabilized, presintered zirconium dioxide for milled production of crowns and bridges frameworks on commercial CAD/CAM systems or handoperated copy-milling machines, with outstanding biocompatibility and high resistance against tension and pressure. Dental Blanks made from DD Bio Z or DD Bio Z-transpa are indicated for crowns, multi-unit bridges and inlay bridges. Applications include both anterior and posterior bridges.

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Clinical and Non-Clinical Testing	Dental Direkt of Amerika UG (haftungsbeschraenkt) did not conduct, nor rely upon, clinical tests to determine substantial equivalence. Non-clinical testing was performed in order to validate the design against the company's specified design requirements, and to assure conformance with the following voluntary design standards: ANSI ADA Specifications No. 69:1999 ISO 6872:2008
Risk Management	The device has been designed to either completely eliminate or mitigate known health hazards associated with the use of the device. Health hazard risk reduction has been accomplished by rigorous application of a risk management program according to ISO 14971 "Medical devices – Application of risk management to medical devices".
Technological characteristics	The technological characteristics between the predicate and proposed devices are identical. There is no difference in fundamental scientific technology. They are made from the same materials and have the same intended use.
Substantial Equivalence Conclusion	Dental Direkt of Amerika UG (haftungsbeschraenkt) believes that DD Bio Z and DD Bio Z-transpa are as safe and effective as the predicate devices when used as instructed by knowledgeable and trained personnel, and are substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Gerhard de Boer
General Manager
Dental Direkt of Amerika UG (haftungsbeschraenkt)
Pappelweg 6
32139 Spenge
GERMANY

FEB 2 4 2010

Re: K093748
Trade/Device Name: DD Bio Z, DD Bio Z-transpa
Regulation Number: 21CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: January 29, 2010
Received: February 3, 2010

Dear Mr. de Boer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093748

Device Name: DD Bio Z, DD Bio Z-transpa

Indications for Use:

Dental Blanks made from DD Bio Z or DD Bio Z-transpa are indicated for crowns, multi-unit bridges and inlay bridges. Applications include both anterior and posterior bridges.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

RSBetz MS for Dr. K.P. Mulroy
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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